Annual Certification of Drug Product Listings

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Drug Listing Certification

- Background – regulatory, problems encountered, new regulatory requirement
- Who must certify, what must be certified, and when do they do it?
- What will happen if a product is not certified?
- Common Validation Errors

Challenge Questions

- Can I submit a Blanket No Changes Certification SPL prior to October 1 during a calendar year?
- If I listed or updated a product in the current calendar year, do I need to ensure that I certify that product between Oct. 1 - Dec. 31?

Background

To start with, here's what companies are required to do:

Section 510(j)(2)(B) of the Food Drug And Cosmetic Act requires that registrants to delist any discontinued product on file every June or December

Section 510(j)(2)(D) of the Food Drug And Cosmetic Act requires that registrants to send in any material changes to any listing already on file every June or December

Background

In 2016 – a new 21 CFR 207 was published (August) and implemented (November).

21 CFR 207.57 (b)(2) *For each listed drug, certify that no changes subject to reporting under paragraph (b)(1)(iv) of this section have occurred if no such changes have occurred since the last review and update. If a drug is discontinued and FDA has received the information required under paragraph (b)(1)(ii) of this section, no further certifications are necessary for the discontinued drug. After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single "no changes" certification during the annual registration update under §207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.*

As a result, there is now an annual requirement to update your listing or certify that no changes have occurred, similar to registration requirements.

Who Must Certify and When?

A new Certification SPL must be created every year (new Set ID every year).

Since the ultimate responsibility for submitting product listings lies with the registered establishment, certification of product listings is also the responsibility of the registered establishments.

Certification SPL submissions will ONLY be accepted during the registration renewal period of October through December. Outside of that window, individual product listing SPLs must be used to update (or renew) a listing.

What Must Be Certified?

At the time of reregistration in the Fall, **every active listing on file** with the FDA that has not been updated within the current calendar year must be certified that no changes have occurred in order to remain active for the coming year.

Only electronic (SPL) listings can be certified. Any drug last updated in paper prior to June 2009 must first be submitted electronically.

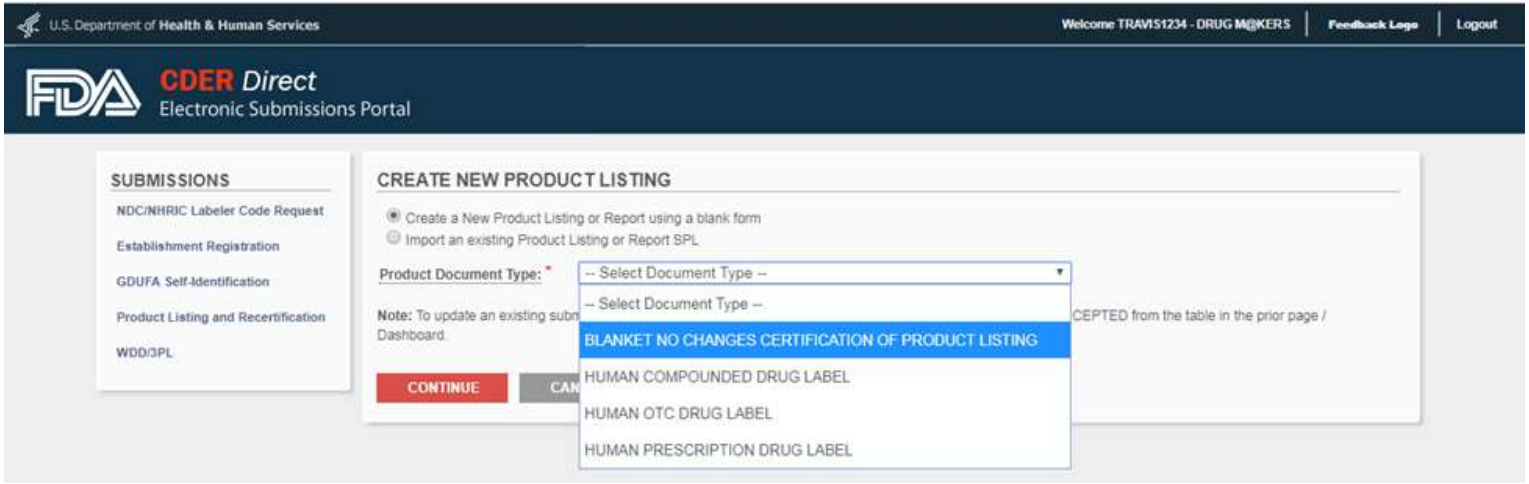
What Happens to an Uncertified Product?

Any NDC product code which has not been updated during the calendar year, or certified during the October to December registration renew period **will be considered expired** on January 1st of the following year.

All expired listings will be removed/notated in the NDC Directory and Unfinished Drug download files.

The only way to reinstate an expired listing is to submit an updated product listing SPL (with same setID as previous version)

What Does Blanket No Changes Certification Look Like?



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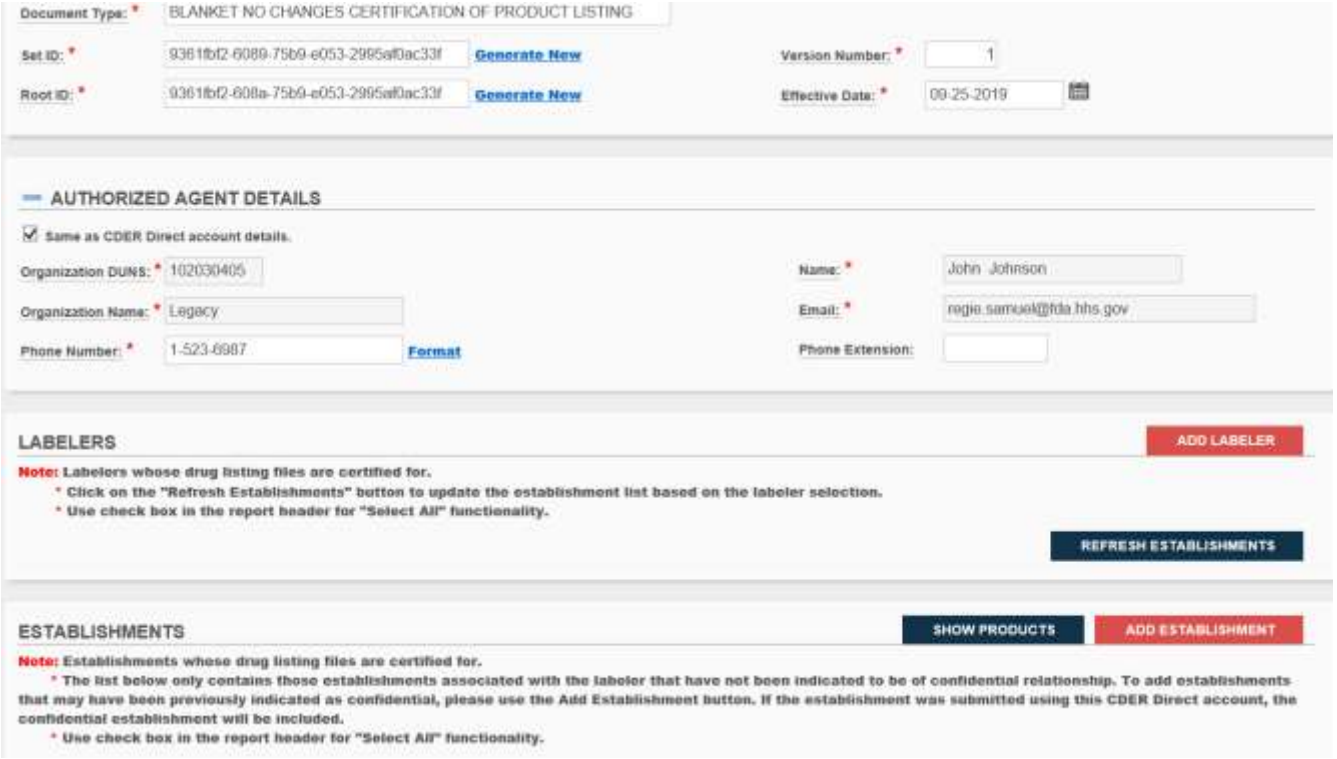


Validation Errors Identified

- Blanket No Changes Certification of Product Listing documents must be submitted during the time frame October 1st through December 31st of each year.

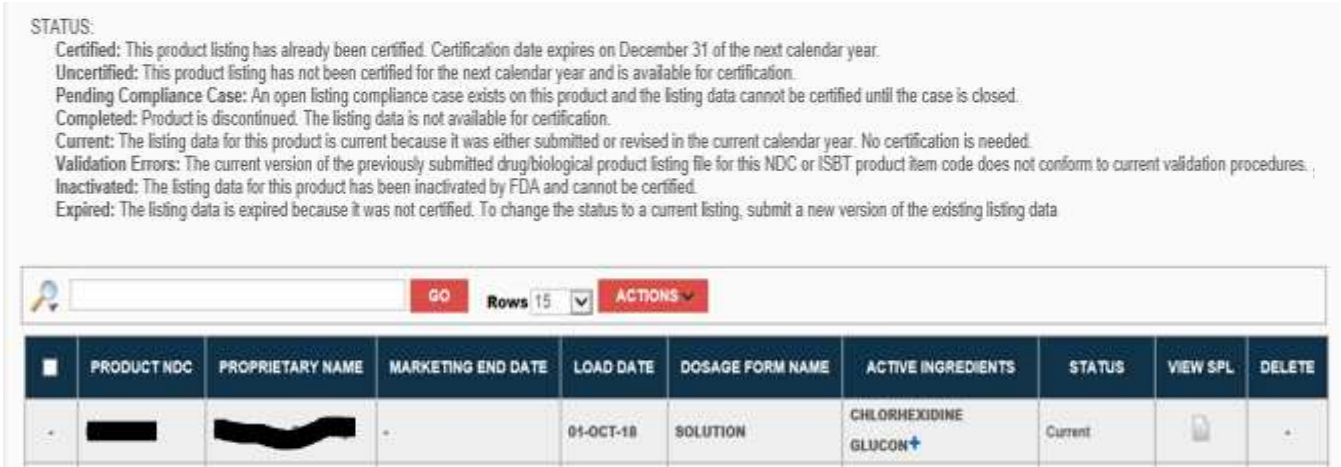
When to Use the Blanket No Changes Certification

- Listing information contained in a Product Listing SPL is fully accurate, including establishment information

- Quickly certify many drug products for a firm

**Pay attention to the Product Status information for a product in the Blanket No Changes Certification*

Understanding Product Status



STATUS:

Certified: This product listing has already been certified. Certification date expires on December 31 of the next calendar year.
Uncertified: This product listing has not been certified for the next calendar year and is available for certification.
Pending Compliance Case: An open listing compliance case exists on this product and the listing data cannot be certified until the case is closed.
Completed: Product is discontinued. The listing data is not available for certification.
Current: The listing data for this product is current because it was either submitted or revised in the current calendar year. No certification is needed.
Validation Errors: The current version of the previously submitted drug/biological product listing file for this NDC or ISBT product item code does not conform to current validation procedures.
Inactivated: The listing data for this product has been inactivated by FDA and cannot be certified.
Expired: The listing data is expired because it was not certified. To change the status to a current listing, submit a new version of the existing listing data

GO Rows 15 ACTIONS

	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	VIEW SPL	DELETE
-	[redacted]	[redacted]	-	01-OCT-18	SOLUTION	CHLORHEXIDINE GLUCON+	Current		-

Understanding Product Status

Certified: This product listing has already been certified. Certification date expires on December 31 of the next calendar year.

Uncertified: This product listing has not been certified for the next calendar year and is available for certification.

Pending Compliance Case: An open listing compliance case exists on this product and the listing data cannot be certified until the case is closed.

Understanding Product Status

Completed: Product is discontinued. The listing data is not available for certification.

Current: The listing data for this product is current because it was either submitted or revised in the current calendar year. No certification is needed.

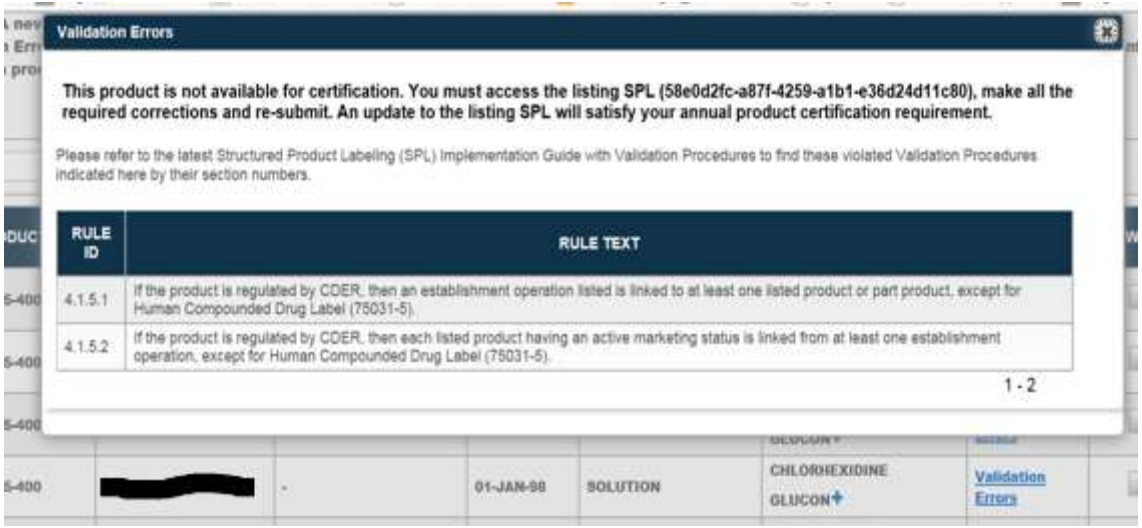
Validation Errors: The current version of the previously submitted drug/biological product listing file for this NDC or ISBT product item code does not conform to current validation procedures.

Understanding Product Status

Inactivated: The listing data for this product has been inactivated by FDA and cannot be certified.

Expired: The listing data is expired because it was not certified. To change the status to a current listing, submit a new version of the existing listing data

Validation Errors Identified



Validation Errors Identified

- This product is not available for certification. You must access the listing SPL (xxxxxxxx-xxxx-xxxx-xxxx-xxxxxxxxxxxx), make all the required corrections and re-submit. An update to the listing SPL will satisfy your annual product certification requirement.

Validation Errors Identified

- The establishment id (DUNS Number) has been submitted in a document of type "Establishment Registration" (51725-0) on or after October 1st of the previous year, or, if earlier, that Establishment Registration has been followed by a document of type "No Change Notification" (53410-7) between October 1st and December 31st of the previous or the current year.

- The NDC or ISBT product item code has been listed as the top-level product in a listing file on or after January 1st of the previous year, or certified in a Blanket No Change Certification of Product Listing Data (86445-4) file on or after October 1st but on or before December 31st of the previous year.

To Sum It Up

- **Every active listing on file** with the FDA that has not been updated within the current calendar year must be certified that no changes have occurred in order to remain active for the coming year.
- Certification SPLs are only submitted during the annual re-registration period October 1 – December 31
- Products that are not certified will be considered expired and removed from publication on January 1 of the following year.
- Products that are expired, delisted, or have a listing deficiency or “validation errors” cannot be certified and must be updated with a full product listing SPL
- Products under the category of “Unapproved Drug for use in Drug Shortage” cannot be certified

Thank You for Keeping Your Drug Listings Up-to-Date!

Drug Listing Inactivation

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Learning Objectives

- Describe circumstances under which a drug listing data is inactivated.
- Provide FDA's drug listing inactivation time periods.
- Describe how an inactivated drug listing data is reactivated.

Challenge Questions

- Will inactivated data continue to be published?
- How an inactivated record is reactivated?
- Is the inactivated data published online?

Drug Listing Requirements

- **Section 510(b) of the FD&C Act** requires that drug establishments register annually on or before December 31 each year (Oct-Dec renewal period)

- **Section 510(j)of the FD&C Act** requires that registrants provide a list of all drugs manufactured for commercial distribution at the time of registration

- **Section 510(j)(2)(D) of the FD&C Act** requires that registrants send in any material changes to any listing already on file every June or December

2016 Revision

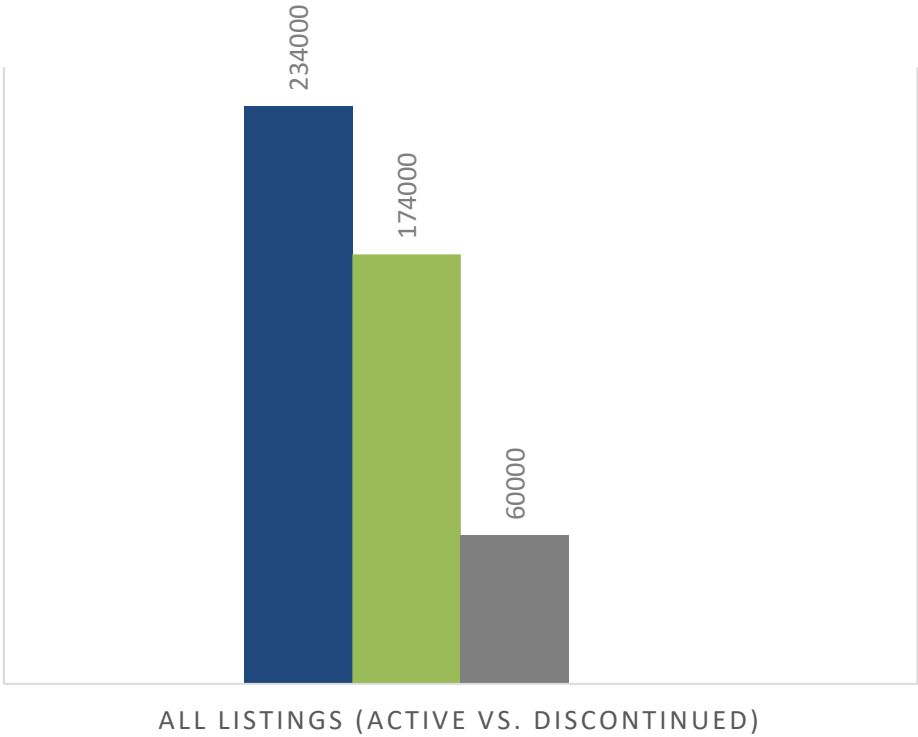
- 21 CFR 207.57 (b)(2)

  After initial electronic listing, registrants may satisfy the listing update requirement with respect to unchanged listing information by making a single “no changes” certification during the annual registration update under §207.29(b) applicable to all of the registrant's listed drugs for which no changes have been made since the previous annual registration update.

As of October 2019

- Over 234,000 drug listing records submitted to FDA
- Over 174,000 drugs reported to be actively marketed
- Over 40,000 of those were never certified
- Over 25,000 of those were never updated

An Overview



ALL LISTINGS (ACTIVE VS. DISCONTINUED)

ACTIVE LISTINGS (NEVER CERTIFIED AND NEVER UPDATED)

Inactivation Core

FDA Inactivation

- FRN published on August 14, 2019
- Listing data will be inactivated:
  - Lack of annual certification
  - Identification of manufacturing establishment not duly registered with FDA

Inactivation Timing

- Started 30 days after publication of the FRN
- FDA annual inactivation periods:
  - January of each calendar year
  - July of each calendar year

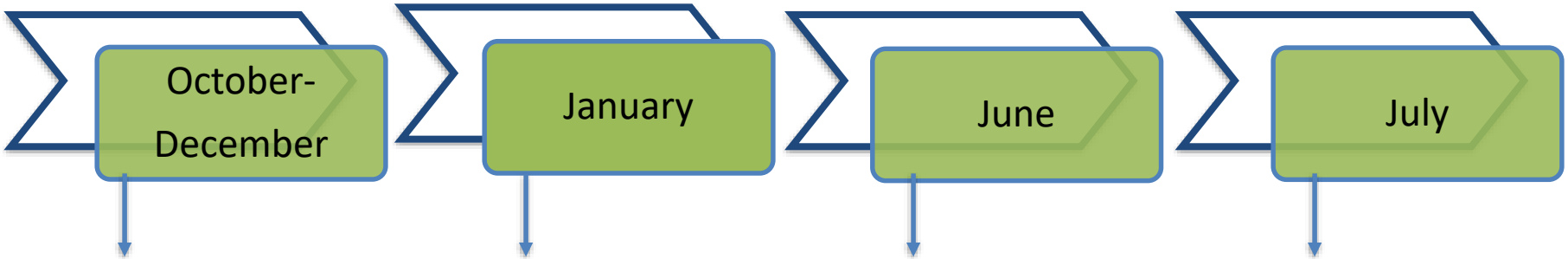
January Inactivation Period

- Drug listing certification requirements
- Expired listing files
- How to reactivate
  - Listing certification SPL not available
  - Listing revisions and updates

July Inactivation Period

- Registration update requirements
  - No later than 30 calendar days (closing or selling)
  - Annual review and update requirement
- Drug listing update requirements
  - June and December, at the minimum

Inactivation – A Timeline



- Renew registration
- Certify drug listing

- Uncertified NDCs will be inactivated

- Update drug listing
  - Update establishments
  - Discontinue with future marketing end date if no longer manufactured

- NDCs associated with unregistered establishments will be inactivated

Inactivation Process

- Started in September 2019
- Notification letters are emailed to the *labeler* contact information
- Inactivation SPLs are generated by FDA
- Data is removed from the NDC Directory search

DailyMed

- Inactivated NDCs are transmitted to DailyMed in the evening of inactivation
  - At this time inactivation information is not published on DailyMed
  - At this time inactivated data is not removed from DailyMed

NSDE File

- Two new columns were added to the NSDE file
  - FDA Inactivation Date
  - FDA Reactivation Date
- The Inactivation and Reactivation Dates are added to NSDE File a business day after

Definitions

- Inactivation Date: The date on which registration or listing data was inactivated by FDA due to inaccuracies, incompleteness or incompliance

- Reactivation Date: The date on which a previously FDA inactivated registration or listing data is reactivated

Compliance Inactivation

- Applicable to compliance cases
- Both registration and listing
- Reactivation through updated SPL requires closure of the compliance case

Published Data

- Inactivated NDCs are published on the NDC Directory page:


NDC Directory

- Search National Drug Code Directory
  Searchable database
- NDC Database File - Text Version (Zip Format)
  Last updated:10/18/2019
- NDC Database File - Excel Version (Zip Format)
  Last updated:10/18/2019
- NDC Database Excluded Packages and Products (Zip Format)
  Last updated:10/18/2019
- NDC Product File Definitions
  Product File Data Elements, Definitions, and Notes
- NDC Package File Definitions
  Package File Data Elements, Definitions, and Notes

- Includes packages and products files
- NDC_Exclude_Flag = I

Reactivation

- Inactivated data can be reactivated
  - Listing certification SPL is not available for inactivated data
  - A listing update will automatically reactivate an inactivated listing data
    - Next Business Day
    - Submissions in response to compliance inactivation cases must be reviewed by compliance officer prior to reactivation

To date…

9,289 drug listing data has been inactivated

Questions?

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